



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,312	12/30/2003	Jessica R. DesNoyer	50623.313	1694

7590 04/18/2006

Cameron Kerrigan
Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111

EXAMINER

LAMB, BRENDA A

ART UNIT	PAPER NUMBER
----------	--------------

1734

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/750,312

Applicant(s)

DESNOYER ET AL.

Examiner

Brenda A. Lamb

Art Unit

1734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,11,13,14 and 16-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9,11,13,14 and 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1734

Claims 1,4-9,11,13,14,16-17,19 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation in claim 17 that the mandrel body has one of the depicted configurations is improper since claims cannot refer to drawings (see 37 CFR 1.58). The recitation in claim 16 that the mandrel body has shape selected from the group consisting of configuration 2,3,4,5,6 or 7 is indefinite since it is unclear what the configuration encompasses. Claims 1,9,16-17,19,23,24 are confusing since it is unclear whether applicant is claiming combination of mandrel and stent especially in view that dependent claims refer to mandrel or support and not the combination of the stent and mandrel/support.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Claims 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation in claim 17 that the mandrel body has one of the depicted configurations is improper since claims cannot refer to drawings (see 37 CFR 1.58). The recitation in claim 16 that the mandrel body has shape selected from the group consisting of configuration 2,3,4,5,6 or 7 is indefinite since it is unclear what the recited configuration encompasses. Claims 1,9,16-17,19,23,24 are confusing since it is unclear whether applicant is claiming combination of mandrel and stent especially in view that the dependent claims refer to the mandrel or support and not the combination of the stent and mandrel/support.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-5, 9, 11, 13-14, 16-19 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hattler et al 4,846,791.

Hattler et al teaches the design of a mandrel as depicted in Figures 3 and Figures 12- 13 supporting a catheter or stent comprising a mandrel body capable of being inserted at least partially into a longitudinal bore of a stent, wherein the mandrel body having a shape within the scope of the claims 16-17. Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). With respect to claim 23, Hattler et al teaches in drawings which include Figures 12-13 a mandrel to support a catheter or stent comprising: a member to penetrate at least partially into a longitudinal bore of a stent, the member including outwardly projecting integral walls disposed around the circumference of the mandrel, wherein each of the walls converge with its neighboring wall at an angle. Hattler et al is capable of supporting a catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in

which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). With respect to claim 18, Hattler et al teaches in drawings which includes Figures 15a and 16 a mandrel to support a catheter or stent comprising: a member to penetrate at least partially into a longitudinal bore of a stent, the member including 3 pairs of opposing parallel sides (the opposing sides from the opposing triangles of the above cited mandrels). Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). With respect to claim 19, Hattler et al teaches as depicted in the drawings which includes Figure 16 the design of a mandrel to support a catheter or stent comprising: a member to penetrate at least partially into a longitudinal bore of a stent during the application of a coating substance, the member including 6 sides and each side wall surface is non-parallel with its neighboring side wall surface. Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). With respect to claims 9, 11 and 13-14,

Hattler et al teaches the mandrel extends the entire length of the catheter or stent (see column 4 lines 64-66). Hattler et al shows the mandrel is comprised of a member including integrally formed walls that have a shape and length within the scope of the claims (see Figures 12-13 and 16). Hattler et al is capable of supporting the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ 2d 1647 (1987). With respect to claims 1, 4-5 and 24-25, Hattler et al shows as depicted in Figures 1-3 a stent mandrel support supporting a catheter or stent comprising: a first member (protrusions arranged at one end of the mandrel) to contact a first end of the stent; a second member (protrusions arranged at the opposite end of the mandrel) to contact a second end of the stent; and a third member connecting the first member to the second member and extending through a longitudinal bore of the stent, the third member having at least least three walls 34 and these wall 34 are shaped and/or sized to substantially prevent a coating from being formed on a luminal surface of the catheter or stent. Hattler et al shows the third member has a plurality of spikes and these spikes contact the luminal surface. Hattler et al teaches the divider extends the entire length of the catheter or stent (see column 4 lines 64-66). Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed

Art Unit: 1734

apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987).

Claims 6-8 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hattler et al.

Hattler et al is applied for the reasons noted above. Hattler et al fails to teach the cross-section of the third member is within the scope of claims 7-8. Hattler et al teaches the third member can have shapes other than triangular such as cross-shaped or star-shaped. However, it would have been obvious to modify the Hattler et al mandrel by providing the third member with a shape within the scope of claims 7-8 since Hattler et al teaches the third member can have shapes other than triangular such as cross-shaped or star-shaped obviously to provide greater support of the catheter or stent. With respect to claim 6, Hattler et al fails to teach that the spikes do not contact the luminal of the stent or catheter. Hattler et al teaches that the geometry of the divider may or may not require protrusions to provide support necessary to prevent collapse of the lumen within the catheter or stent. Therefore it would have been obvious to modify the Hattler et al mandrel such that the spikes of the third member do not have to touch or contact the luminal of the stent as long as the number of protrusions on the third member are sufficient to prevent collapse of the luminal within the catheter or stent for the obvious reason of providing a plurality of discrete support points – enable one to provide continued support for the catheter despite wear of the one of the discrete protrusions. With respect to claims 20-22, Hattler et al teaches as depicted in the

Art Unit: 1734

drawings which include Figure 3 the design of a mandrel to support a catheter or stent comprising: a core section having at least three sides and a wall extending from each of the sides in an outwardly direction. Hattler et al shows the walls are triangular in cross section and core have a shape within the scope of the claims. Hattler et al fails to teach that the core is solid and the wall is coupled to and extending from each of the sides in an outwardly direction. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the mandrel by coupling a wall to each of the sides of the Hattler et al core section since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177,179. Further, Hattler et al teaches at column 6 lines 66-67 that the divider can be either hollow or solid. Therefore, it would have been obvious given the modified Hattler et al apparatus as discussed above to construct the core section as a solid core section rather than a hollow core section since Hattler et al teaches at column 6 lines 66-67 that the divider can be either hollow or solid and obvious to do so to increase the structural stability of the mandrel. Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ 2d 1647 (1987).

Applicant's arguments filed 2/1/2006 have been fully considered but they are not persuasive. Applicant's argument that Hattler et al fails to teach a stent mandrel support

Art Unit: 1734

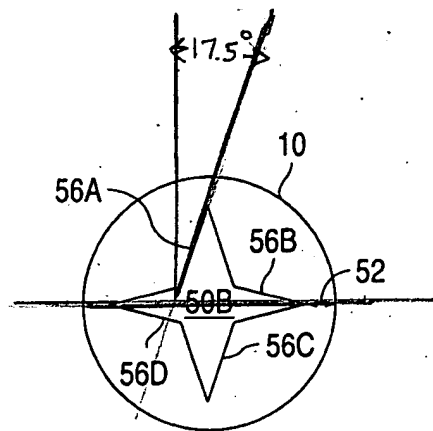
supporting a stent is found to be non-persuasive. Hattler et al mandrel is capable of supporting a stent since it teaches all the claimed structural elements of the mandrel set forth in the body of the claim, that is, a first member to contact a first end of the substrate, a second member to contact a second end of the substrate, and a third member connecting the first member to the second member and extending through a longitudinal bore of the substrate, the third member shaped and/or sized to eliminate or substantially prevent a coating from being formed on a luminal surface of the substrate during application of a coating substance to the substrate. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Further, it is noted that the American Heritage Dictionary of the English Language, Fourth Ed. (2000) defines a **stent** as "a slender thread, rod, or **catheter** inserted into a tubular structure, such as a blood vessel, to provide support during or after anastomosis." Applicant's argument that Hattler et al is non-analogous art in that it is not directed to a stent mandrel support supporting a stent for use during coating is found to be non-persuasive. Hattler et al shows a divider supporting a hollow tube to be inserted in a vessel within the body (catheter) as shown in Figure 1 thereby reading on the applicant's claimed mandrel. Further, it is noted that the American Heritage Dictionary of the English Language, Fourth Ed. (2000) defines a **stent** as "a slender

Art Unit: 1734

thread, rod, or **catheter** inserted into a tubular structure, such as a blood vessel, to provide support during or after anastomosis." Finally, the Hattler et al mandrel is capable of holding the hollow tube such as a stent or catheter during coating since it teaches every claimed element of the apparatus/mandrel. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Applicant's argument that the rejection of claims 16-17 under 35 USC 112, second paragraph is disagreed with since incorporating the figures into claim 17 is not improper and is more practical, precise and definite than words and referring to configurations such as set forth in claim 16 which in turn refers in the specification to drawings is definite not indefinite since applicant is entitled by his or her own lexicographer is found to be non-persuasive. It is noted that MPEP 2173.05 states that incorporation by reference to a specific figure is permitted only in exceptional circumstances where there is no practical way to define applicant's invention in words and where it is more concise to incorporate the reference than duplicate a drawing or table into the claim. The examiner notes the specification describes each of the configuration using words at pages 17-20. Therefore, in contrast to applicant's

Art Unit: 1734

arguments, there is a practical way to describe the invention, different configurations of the mandrel body, in words and therefore, the examiner maintains that the inclusion of the drawings in claim 17 to depict the shape of the mandrel body is improper (see 37 CFR 1.58). Further, although the examiner agrees that applicant can be his or her own lexicographer, the examiner maintains that claim 16 is indefinite since it unclear what the claim encompasses, that is, it fails to clarify the metes and bounds of the claim. For example, applicant refers to configuration 2 as depicted in figures which include Figure 5A and it is unclear when applicant claims the mandrel body has the shape of configuration 2 whether applicant intends to claim that the angle of the inclined side of the vertically oriented upper spike with respect to a normal to the horizontal axis which passes through the center of the star and the peaks of the horizontal spikes is about 17.5 degrees or not. See the drawing below:

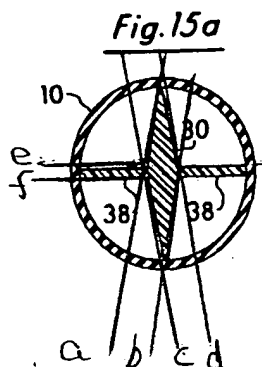
**FIG. 5A**

Applicant's argument that Figures 15a and Figure 16 fails to include 3 pairs of opposing parallel sides is found to be non-persuasive. The examiner maintains that

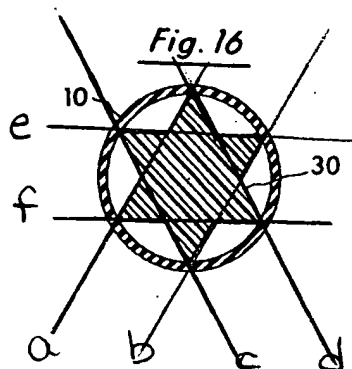
Art Unit: 1734

drawings 15a and 16 include at least 3 pairs of opposing parallel sides as depicted

below.



The at least 3 pairs of
opposing parallel
Sides:
1st pair - a, b
2nd pair - c, d
3rd pair - e, f



The at least 3 pairs
of opposing parallel
Sides:
1st pair - a, b
2nd pair - c, d
3rd pair - e, f

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

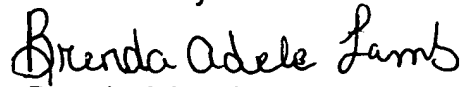
CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1734

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Brenda A. Lamb at telephone number (571) 272-1231. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday with alternate Wednesday off.


Brenda A Lamb
Examiner
Art Unit 1734